Complete Summary

GUIDELINE TITLE

Endoscopic retrograde cholangiopancreatography (ERCP) for diagnosis and therapy.

BIBLIOGRAPHIC SOURCE(S)

Endoscopic retrograde cholangiopancreatography (ERCP) for diagnosis and therapy. NIH Consens Statement Online 2002 Jan 14-16;19(1):1-23.

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE
METHODOLOGY - including Rating Scheme and Cost Analysis
RECOMMENDATIONS
EVIDENCE SUPPORTING THE RECOMMENDATIONS
BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS
QUALIFYING STATEMENTS
IMPLEMENTATION OF THE GUIDELINE
INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES
IDENTIFYING INFORMATION AND AVAILABILITY
DISCLAIMER

SCOPE

DISEASE/CONDITION(S)

Pancreatic or hepatobiliary diseases including gallstones and their complications, pancreatic and biliary cancers, pancreatitis and its complications, and pancreaticobiliary pain

GUIDELINE CATEGORY

Assessment of Therapeutic Effectiveness
Diagnosis
Evaluation
Management

CLINICAL SPECIALTY

Gastroenterology
Internal Medicine
Oncology
Radiology
Surgery

INTENDED USERS

Health Care Providers
Patients
Physicians

GUIDELINE OBJECTIVE(S)

- To provide health care providers, patients, and the general public with a responsible assessment of currently available data regarding the use of endoscopic retrograde cholangiopancreatography (ERCP) for diagnosis and therapy.
- To address the following key questions:
    - What is the role of ERCP in gallstone disease?
    - What is the role of ERCP in pancreatic and biliary malignancy?
    - What is the role of ERCP in pancreatitis?
    - What is the role of ERCP in abdominal pain of possible pancreatic or biliary origin?
    - What are the factors determining adverse events or success?
    - What future research directions are needed?

TARGET POPULATION

Patients with known or suspected common bile duct stones, pancreaticobiliary malignancy, pancreatitis, or abdominal pain of possible pancreaticobiliary origin

INTERVENTIONS AND PRACTICES CONSIDERED

Endoscopic retrograde cholangiopancreatography (ERCP) as a diagnostic or therapeutic strategy compared to alternative practices, including:

1. Magnetic resonance cholangiopancreatography (MRCP)
2. Magnetic resonance imaging (MRI)
3. Endoscopic ultrasound (EUS)
4. Computed tomographic cholangiography (CTC)
5. Contrast-enhanced computed tomography (CT) scanning
6. CT angiography (CTA)
7. Magnetic resonance angiography (MRA)
8. Laparoscopic cholecystectomy
9. Sphincter of Oddi manometry (SOM)
10. Stent placement
11. Biliary scintigraphy
12. Endoscopic sphincterotomy (ES)
13. Drug therapy (anticholinergics, antidepressants, nonspecific pain relievers, and/or calcium-channel blockers)

MAJOR OUTCOMES CONSIDERED

- For diagnostic performance studies, outcomes of interest were test performance characteristics (i.e., sensitivity and specificity)
- For therapeutic outcome studies, the primary outcomes of interest were:
    - Measures of technical success (e.g., removal of stone, relief of obstruction, cyst drainage, need for repeat procedure or placement of stent).
    - Measures of clinical success (e.g., survival, quality of life, performance scores, relief of jaundice, relief of infection, symptom scores, or pain scores).
    - Resource utilization (e.g., hospitalization, perioperative care, return to work, intensity of post-procedure care).
    - Procedure-related morbidity (e.g., stent-related problems, cholangitis, sepsis, sedation-related outcomes, bleeding, perforation, pancreatitis, long-term effects of sphincterotomy, mortality).
- For studies of factors predicting endoscopic retrograde cholangiopancreatography (ERCP) complications, the primary outcomes of interest were measures of relative risk or predictive value associated with patient, procedure, or operator factors.

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Search Strategy for the Identification of Articles

The National Library of Medicine (NLM) staff conducted a comprehensive literature search for journal articles on endoscopic retrograde cholangiopancreatography (ERCP) from the PubMed®/MEDLINE®, BIOSIS, EMBASE, and SciSearch® databases with a publication date from 1980 through August 13, 2001. Articles which had been indexed to the National Library of Medicine Medical Subject Heading (MeSH®) "cholangiopancreatography, endoscopic retrograde" as well as those containing ERCP synonyms and text word combinations were retrieved (see the original guideline document for a complete listing).

Excluded from the search results were articles that:

- Were written in a foreign language.
- Did not have abstracts as a part of the online record in any of the databases searched.
- Did not include human subjects.
- Contained reports of only a single case.

The literature search for Topic 1c of the original guideline document on prediction of common bile duct stones and for additional studies selected by the secondary selection criteria for Topics 3 and 4 of the original guideline document used a streamlined search process to identify key articles addressing the clinical issue of interest. Reference lists from these articles were reviewed, focused MEDLINE searches were performed, and related articles were identified.

The Technical Advisory Group and peer reviewers for this project were asked to inform the project team of any studies relevant to the key questions addressed in this evidence report that were not retrieved by either of the search strategies.

Search Results

The online searches of the PubMed, EMBASE, BIOSIS, and SciSearch databases in conjunction with additional citations identified through manual searching yielded a total of 5,698 titles and abstracts for review. Based on review of abstracts, 789 articles were selected for review in full text.

Approximately 117 of these articles were excluded as review articles. Primary and secondary selection criteria were applied to articles identified as potential clinical trial reports. This process yielded a total of 149 included studies for the review of evidence.

Study Selection Criteria

Primary Selection Criteria

The selection criteria for all topics in this report were:

1. Full-length report in peer-reviewed medical journals
2. Published in English
3. Reported outcomes relevant to this systematic review
4. Where there were multiple reports of a single study, only the report judged to be most recent and complete, based on number of included patients and length of follow-up, was included. If additional relevant outcomes were included in the duplicate reports, these data were abstracted and added to the data from the primary report with citation to the supplementary articles.
5. Prospective in design, or if retrospective, enrolled consecutive patients or used appropriate sampling methods (e.g., case-control sampling method)

In order to keep readers informed of ongoing studies, studies published only in abstract form since 1999 and judged to be important are noted in this systematic review; but data were not abstracted into the evidence tables.

Studies of diagnostic performance met the following additional selection criteria:

1. Compared ERCP and at least one of the relevant diagnostic alternatives or compared two ERCP alternatives
2. Subjected at least 90 percent of participants to both ERCP and the relevant diagnostic alternative
3. Addressed a relevant patient population

4. Included at least 25 subjects
5. Reported sufficient information to be able to calculate 2x2 contingency tables of diagnostic performance

Studies of therapeutic outcomes met the following additional selection criteria:

1. Compared ERCP strategies with at least one of the relevant therapeutic alternatives
2. Addressed a relevant patient population
3. Included at least 25 subjects in each treatment group being analyzed separately
4. Reported on at least one relevant outcome measure
5. Were a contemporaneous comparison studies. If not contemporaneous, the populations and treatment settings were comparable.

Studies of predictors of ERCP complications met the following additional selection criteria:

1. Included a multivariable analysis of the relationship between patient, procedure, or operator factors and ERCP complications
2. Enrolled at least 100 patients if a cohort study, or at least 25 cases if a case-control study.
3. Addressed potential confounding variables in either the selection of subjects or analysis.

Studies on the prediction of common bile duct stones met the following additional selection criteria:

1. Reported the association of either (a) specific risk factors of interest and the presence of a common bile duct stone (specific risk factors of interest were jaundice, liver function test results, and ultrasound finding of a dilated common bile duct), or (b) a prediction rule or model predicting likelihood of having a common bile duct stone and the presence of a common bile duct stone
2. Enrolled at least 100 patients
3. Reported sufficient information to be able to calculate 2x2 contingency tables of diagnostic performance in the prediction of presence or absence of a common bile duct stone

Secondary Selection Criteria

There was a paucity of literature that met the primary selection criteria for questions on ERCP treatment of chronic pancreatitis (Topic 3b) and ERCP treatment of chronic abdominal pain of possible pancreaticobiliary origin (Topic 4b). In order to examine these questions, the original study selection criteria were relaxed for these topics to include:

1. Randomized controlled trials or otherwise concurrently controlled studies of an ERCP intervention compared to a relevant therapeutic alternative, regardless of sample size for pancreatitis.

2. Single arm pre-post-intervention studies which selected a well-defined population with a predictable natural history ascertained by baseline evaluation over 3 months. These studies must also have used an appropriate well-designed outcome measure over at least 6 months of follow-up.

NUMBER OF SOURCE DOCUMENTS

149 studies were included in the review of evidence

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

One reviewer performed primary data abstraction of all data elements into the evidence tables, and a second reviewer checked accuracy of the evidence tables. Disagreements were resolved between the two reviewers, or if necessary, in consultation with the Evidence-based Practice Center Director or members of the Technical Advisory Group.

Study Quality Assessment

The approach to assessing the quality of evidence used domains commonly recognized as important in the literature on study quality. Quality criteria were developed for each of the three types of studies included in this systematic review: studies of therapeutic effectiveness; studies of diagnostic performance; and multivariable regressions analysis. For many topics addressed in this evidence review, studies meeting the most rigorous standards of quality do not exist. Thus, the main purpose of quality assessment in this systematic review is to discriminate between the better and lesser quality studies in the available evidence base.

For studies of therapeutic efficacy, the approach to quality assessment was adapted from that of the U.S. Public Health Preventive Services Task Force. Study quality domains of interest were: initial assembly of comparable groups (includes adequacy of randomization and controls for confounders); maintenance of comparable groups (includes attrition, crossovers, adherence, contamination); comparable performance of interventions; comparable measurements (unbiased, reliable, and valid); and appropriate analysis of outcomes (includes intent-to-treat analysis). A study was rated as "Good" if it clearly met all quality parameters. A study was rated "Fair" if it reasonably met these parameters and had no fatal

flaw. A study was rated "Poor" if it was fatally flawed on one or more parameters (e.g., if comparable groups were not assembled or maintained or outcome measures were invalid or not applied equally among groups).

For studies of diagnostic performance, criteria for assessing study quality were developed using key references in the field of study quality assessment. The selection criteria used for this systematic review eliminated poor quality studies from inclusion. Study quality domains of interest to discriminate between good and fair quality studies were: enrollment of representative subjects (includes appropriate spectrum of patients, unbiased enrollment, complete enrollment of eligible patients, accounting for all eligible subjects); endoscopic retrograde cholangiopancreatography (ERCP) interpreted independently of diagnostic alternative; and diagnostic alternative interpreted independently from endoscopic retrograde cholangiopancreatography. As relevant, issues of suitability and interpretation of reference standards are addressed qualitatively in the discussion of each question.

For multivariable logistic regression analysis studies, the quality domains of interest were the degree of over-fitting present in the multivariable models, the nature of statistical reporting, and the use of procedures to establish internal validity. Degree of over-fitting was assessed using the ratio of the number of endpoints divided by the number of candidate variables in the model and was classified as satisfactory (ratio >10) to severe (ratio <4).

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus (Consensus Development Conference)

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

A National Institutes of Health (NIH) State-of-the-Science Conference on Endoscopic Retrograde Cholangiopancreatography (ERCP) for Diagnosis and Therapy was convened on January 14–16, 2002. Participants included a non-Federal, non-advocate, 13-member panel representing the fields of gastroenterology, hepatology, clinical epidemiology, oncology, biostatistics, surgery, health services research, radiology, internal medicine, and the public. In addition, experts in these same fields presented data to the panel and to a conference audience of approximately 300.

Answering predefined questions, the panel drafted a statement based on the scientific evidence presented in open forum and the scientific literature. The draft statement was read in its entirety on the final day of the conference and circulated to the audience for comment. The panel then met in executive session to consider the comments received and released a revised statement at the end of the conference.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The draft statement was read in its entirety on the final day of the conference and circulated to the audience for comment. The panel then met in executive session to consider the comments received and released a revised statement at the end of the conference. The statement was made available on the World Wide Web at http://consensus.nih.gov immediately after the conference.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

- In the diagnosis of choledocholithiasis, magnetic resonance cholangiopancreatography (MRCP), endoscopic ultrasound (EUS), and endoscopic retrograde cholangiopancreatography (ERCP) have comparable sensitivity and specificity.
- Patients undergoing cholecystectomy do not require ERCP preoperatively if there is low probability of having choledocholithiasis.
- Laparoscopic common bile duct exploration and post-operative ERCP are both safe and reliable in clearing common bile duct stones.
- ERCP with endoscopic sphincterotomy (ES) and stone removal is a valuable therapeutic modality in choledocholithiasis with jaundice, dilated common bile duct, acute pancreatitis, or cholangitis.
- In patients with pancreatic or biliary cancer, the principal advantage of ERCP is palliation of biliary obstruction when surgery is not elected. In patients who have pancreatic or biliary cancer and who are surgical candidates, there is no established role for preoperative biliary drainage by ERCP.
- Tissue sampling for patients with pancreatic or biliary cancer not undergoing surgery may be achieved by ERCP, but this is not always diagnostic.
- ERCP is the best means to diagnose ampullary cancers.
- ERCP has no role in the diagnosis of acute pancreatitis except when biliary pancreatitis is suspected. In patients with severe biliary pancreatitis, early intervention with ERCP reduces morbidity and mortality compared with delayed ERCP.
- ERCP with appropriate therapy is beneficial in selected patients who have either recurrent pancreatitis or pancreatic pseudocysts.
- Patients with type I sphincter of Oddi dysfunction (SOD) respond to endoscopic sphincterotomy. Patients with type II sphincter of Oddi dysfunction should not undergo diagnostic ERCP alone. If sphincter of Oddi manometer pressures are >40 mmHg, endoscopic sphincterotomy is beneficial in some patients.

- Avoidance of unnecessary ERCP is the best way to reduce the number of complications. ERCP should be avoided if there is a low likelihood of biliary stone or stricture, especially in women with recurrent pain, a normal bilirubin, and no other objective sign of biliary disease.
- Endoscopists performing ERCP should have appropriate training and expertise before performing advanced procedures.
- With newer diagnostic imaging technologies emerging, ERCP is evolving into a predominantly therapeutic procedure.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

Evidence included presentations by experts; a systematic review of the medical literature provided by the Agency for Healthcare Research and Quality; and an extensive bibliography of endoscopic retrograde cholangiopancreatography (ERCP) research papers, prepared by the National Library of Medicine. Scientific evidence was given precedence over clinical anecdotal experience.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Appropriate use of endoscopic retrograde cholangiopancreatography (ERCP) for diagnosis and therapy
- In patients with pancreatic or biliary cancer, the principal advantage of endoscopic retrograde cholangiopancreatography (ERCP) is palliation of biliary obstruction when surgery is not elected.
- In patients with severe biliary pancreatitis, early intervention with ERCP reduces morbidity and mortality compared with delayed ERCP.
- ERCP with appropriate therapy is beneficial in selected patients who have either recurrent pancreatitis or pancreatic pseudocysts.

POTENTIAL HARMS

- The main complication of endoscopic retrograde cholangiopancreatography (ERCP) is pancreatitis. Other complications include hemorrhage, perforation, cholangitis, cholecystitis, stent-related complications, and cardiopulmonary complications. Pancreatitis occurs in about 5 to 7 percent of patients undergoing ERCP, whether for diagnosis or therapy. Complications vary for different indications for ERCP.
- The rate of post-endoscopic sphincterotomy (ES) hemorrhage, about 0.2 to 5 percent, is related to anticoagulation (within 3 days after endoscopic sphincterotomy), coagulopathy, and acute cholangitis.
- Cardiopulmonary complications, while uncommonly related to ERCP, are the leading cause of death from ERCP and occur in older, sicker patients. Such

complications might be lessened by close attention to choice of patients, to sedation and analgesia, and to appropriate collaboration with anesthesiologists to manage high-risk or difficult-to-sedate patients. Cholangitis is a complication of failed or incomplete biliary drainage.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- The statement reflects the panel's assessment of medical knowledge available at the time the statement was written. Thus, it provides a "snapshot in time" of the state of knowledge on the conference topic. When reading the statement, keep in mind that new knowledge is inevitably accumulating through medical research.
- This statement is an independent report of the panel and is not a policy statement of the National Institute of Health (NIH) or the Federal Government.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Resources
Staff Training/Competency Material

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Living with Illness

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Endoscopic retrograde cholangiopancreatography (ERCP) for diagnosis and therapy. NIH Consens Statement Online 2002 Jan 14-16;19(1):1-23.

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2002 Jan 16

GUIDELINE DEVELOPER(S)

National Institutes of Health (NIH) Consensus Development Panel on Endoscopic Retrograde Cholangiopancreatography (ERCP) for Diagnosis and Therapy - Independent Expert Panel

SOURCE(S) OF FUNDING

United States Government

GUIDELINE COMMITTEE

National Institutes of Health (NIH) Consensus Development Panel

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Panel Members: Sidney Cohen, M.D. (Chair) Professor of Medicine, Director, Research Programs Division of Gastroenterology and Hepatology, Jefferson Medical College, Thomas Jefferson University, Philadelphia, Pennsylvania; Bruce R. Bacon, M.D., James F. King, M.D. Endowed Chair in Gastroenterology, Professor of Internal Medicine, Director, Division of Gastroenterology and Hepatology, Saint Louis University School of Medicine, St. Louis, Missouri; Jesse A. Berlin, Sc.D., Professor of Biostatistics, Center for Clinical Epidemiology and Biostatistics School of Medicine, University of Pennsylvania, Philadelphia, Pennsylvania; David Fleischer, M.D., M.A.C.P., Professor of Medicine Mayo School of Medicine, Chair, Division of Gastroenterology and Hepatology, Mayo Clinic Scottsdale, Scottsdale, Arizona; Gail A. Hecht, M.D., Associate Professor of Medicine, Chair, Digestive Diseases and Nutrition, Section of Digestive and Liver Diseases, University of Illinois at Chicago, Chicago, Illinois; Patrick J. Loehrer, Sr., M.D., Professor of Medicine, Department of Medicine, Indiana University Cancer Center, Indiana University, Indianapolis, Indiana; Alfred E. McNair, Jr., M.D., President, Digestive Health Center, Ocean Springs, Mississippi, Assistant Clinical Professor, Tulane University, Past President, Leonidas Berry Society, Atlanta, Georgia; Michael Mulholland, M.D., Ph.D., Professor and Chairman, Department of Surgery, University of Michigan Medical School, Ann Arbor, Michigan; Nancy J. Norton, President, International Foundation for Functional Gastrointestinal Disorders, Boston, Massachusetts; Linda Rabeneck, M.D., M.P.H., Associate Professor of Medicine, Sections of Health, Services Research and Gastroenterology, Baylor College of Medicine, Houston, Texas; David F. Ransohoff, M.D., Professor of Medicine, School of Medicine, University of North

Carolina at Chapel Hill, Chapel Hill, North Carolina; Amnon Sonnenberg, M.D., Professor, Division of Gastroenterology, Department of Internal Medicine, University of New Mexico Health Sciences Center, Albuquerque, New Mexico; Michael W. Vannier, M.D., Professor, Department of Radiology, University of Iowa, Iowa City, Iowa

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

All of the panelists who participated in this conference and contributed to the writing of this statement were identified as having no financial or scientific conflict of interest, and all signed forms attesting to this fact.

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the National Institutes of Health (NIH) Consensus Development Conference Program Web Site.

Print copies: Available from the NIH Consensus Development Program Information Center, PO Box 2577, Kensington, MD 20891; Toll free phone (in U.S.), 1-888-NIH-CONSENSUS (1-888-644-2667); autofax (in U.S.), 1-888-NIH-CONSENSUS (1-888-644-2667); e-mail: consensus_statements@mail.nih.gov.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Endoscopic retrograde cholangiopancreatography. Evidence Report/Technology Assessment: No. 50 AHRQ Publication No. 02-E008. Rockville, MD: Agency for Healthcare Research and Quality. January 2002. Available from the AHRQ Web Site.
- CME Material. Endoscopic retrograde cholangiopancreatography (ERCP) for diagnosis and therapy. 2002 Nov 7. Available from the National Institutes of Health (NIH) Consensus Development Conference Program Web Site.

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on January 14, 2005.

COPYRIGHT STATEMENT

DISCLAIMER

NGC DISCLAIMER

The National Guideline Clearinghouse™ (NGC) does not develop, produce, approve, or endorse the guidelines represented on this site.

All guidelines summarized by NGC and hosted on our site are produced under the auspices of medical specialty societies, relevant professional associations, public or private organizations, other government agencies, health care organizations or plans, and similar entities.

Guidelines represented on the NGC Web site are submitted by guideline developers, and are screened solely to determine that they meet the NGC Inclusion Criteria which may be found at http://www.guideline.gov/about/inclusion.aspx.

NGC, AHRQ, and its contractor ECRI make no warranties concerning the content or clinical efficacy or effectiveness of the clinical practice guidelines and related materials represented on this site. Moreover, the views and opinions of developers or authors of guidelines represented on this site do not necessarily state or reflect those of NGC, AHRQ, or its contractor ECRI, and inclusion or hosting of guidelines in NGC may not be used for advertising or commercial endorsement purposes.

Readers with questions regarding guideline content are directed to contact the guideline developer.

Date Modified: 9/25/2006